Complete Summary

GUIDELINE TITLE

Management of fibromyalgia syndrome in adults.

BIBLIOGRAPHIC SOURCE(S)

University of Texas, School of Nursing, Family Nurse Practitioner Program. Management of fibromyalgia syndrome in adults. Austin (TX): University of Texas, School of Nursing; 2009 May. 14 p. [25 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: University of Texas, School of Nursing, Family Nurse Practitioner Program. Fibromyalgia treatment guideline. Austin (TX): University of Texas, School of Nursing; 2005 May. 13 p. [18 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Fibromyalgia syndrome

GUIDELINE CATEGORY

Diagnosis
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Neurology
Nursing
Rheumatology
Sleep Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

GUIDELINE OBJECTIVE(S)

- To guide practice decisions that integrate medical, pharmacological, and behavioral elements for treatment
- To enhance the quality and functionality of life for the patient
- To interpret and integrate the latest research to effectively manage patients with fibromyalgia
- To delineate the criteria for definite diagnosis and treatment
- To obtain the highest level of patient compliance and satisfaction with therapeutic and pharmacologic management

TARGET POPULATION

Adults who meet the diagnostic criteria for fibromyalgia syndrome

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Use of American College of Rheumatology criteria for diagnosis of fibromyalgia syndrome
2. Fibromyalgia Impact Questionnaire (FIQ)

Management/Treatment

1. Patient and family education (including internet resources) regarding diagnosis, signs and symptoms, and treatment options
2. Nonpharmacological treatment including
    - Aerobic exercise
    - Cognitive behavioral therapy (CBT)
    - Strength training
    - Acupuncture
    - Hypnotherapy

- Biofeedback
- Balneotherapy

3. Pharmacological therapy, including
    - Antidepressants (tricyclic antidepressants, serotonin and norepinephrine reuptake inhibitors, selective serotonin reuptake inhibitors)
    - Anticonvulsants
    - Other medications, such as cyclobenzaprine and tramadol with or without acetaminophen

Note: The following interventions were considered but not recommended: chiropractic therapy, massage therapy, electrotherapy, ultrasound, trigger point exercise, flexibility exercise, opioids, benzodiazepines, nonsteroidal anti-inflammatory drugs, magnesium, guaifenesin, hormonal agents.

MAJOR OUTCOMES CONSIDERED

- Quality of life
- Level of pain
- Sleep disturbance
- Muscle strength
- Physical mobility
- Daily activity functioning

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The following resources were reviewed:

1. Nationally recognized, expert standards established by the American College of Rheumatology Diagnostic Criteria
2. Nationally recognized, expert association literature obtained from uptodate.com, the American Medical Association, and the U.S. Department of Health and Human Services

NUMBER OF SOURCE DOCUMENTS

25

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The U.S. Preventive Services Task Force (USPSTF) grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor).

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Articles were reviewed for applicability for target population and for validity and reliability of research methods and results.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations according to one of five classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms).

A. The USPSTF strongly recommends that clinicians provide the service to eligible patients. The USPSTF found good evidence that the service improves important health outcomes and concludes that benefits substantially outweigh harms.

B. The USPSTF recommends that clinicians provide this service to eligible patients. The USPSTF found at least fair evidence that the service improves important health outcomes and concludes that benefits outweigh harms.

C. The USPSTF makes no recommendation for or against routine provision of the service. The USPSTF found at least fair evidence that the service can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

D. The USPSTF recommends against routinely providing the service to asymptomatic patients. The USPSTF found at least fair evidence that the service is ineffective or that harms outweigh benefits.

I. The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing the service. Evidence that the service is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A draft of the guideline was developed by a group of family nurse practitioner (FNP) students and submitted for review to the FNP faculty. A final review was performed by an external expert, and subsequent changes were made prior to submitting to the guidelines committee.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Strength of recommendations (**A, B, C, D, I**) and quality of evidence (**good, fair, poor**) are defined at the end of the "Major Recommendations" field.

Step 1 – Patient and Family Education

1. Educate the patient about diagnosis, signs and symptoms, and treatment options. Confirm the diagnosis of fibromyalgia (FM) by utilizing 1990 American College of Rheumatology (ACR) diagnostic criteria. Explain that fibromyalgia is a chronic disorder that waxes and wanes that may affect quality of life but not necessarily lifespan. Patients who have signs and symptoms explained by healthcare providers report fewer symptoms and have decreased symptom intensity over time (Huynh, Yanni, & Morgan, 2008) **(Grade A, Evidence Good)**.
2. Provide internet education resources for patients and family through the National FM Association (www.fmaware.org), National Fibromyalgia Research

Association (www.nfra.net), and Fibromyalgia Network (www.fmnetnews.com). Intensive patient education about FM has been shown to improve pain, sleep, fatigue, and quality of life in patients with FM (Goldenberg, Burckhardt, & Crofford, 2004) **(Grade A, Evidence Good)**.

3. Fibromyalgia Impact Questionnaire (FIQ). FIQ is a validated instrument that is used to assess and evaluate the impact of FM on aspects of health and function. This questionnaire is composed of 10 items that relate to physical function, pain level, fatigue, sleep disturbance, anxiety, and depression. FIQ information can be accessed on www.myalgia.com. The patient's baseline score can be compared to subsequent scores obtained after various treatment modalities are trialed to evaluate outcome. (Bennett, 2005) **(Grade A, Evidence Good)**.

Step 2 — Nonpharmacological Treatment

1. Aerobic exercise. Moderately intense aerobic exercise has been shown to improve pain and tender point pain pressure thresholds (Busch et al., 2007). Gradual exercise progression should be advised to avoid an exacerbation of symptoms (Goldenberg, Burckhardt, & Crofford, 2004). A once-daily aerobic fitness program with intensity titrated to the patient's threshold for pain and fatigue promotes adherence and likelihood of improved outcome measures (Huynh, Yanni, & Morgan, 2008) **(Grade A, Evidence Good)**.
2. Cognitive behavioral therapy (CBT). A meta-analysis of controlled studies shows that short-term CBT improves pain, fatigue, mood, and physical function up to 12 months after intervention (Huynh, Yanni, & Morgan, 2008) **(Grade A, Evidence Good)**.
3. Strength training. Mild strength training is helpful with fibromyalgia (Schneider et al., 2009) **(Grade B, Evidence Fair)**.
4. Acupuncture. Moderate reduction of pain in FM patients has been shown with acupuncture treatment (Schneider et al., 2009) **(Grade B, Evidence Fair)**.
5. Hypnotherapy. Reduction of pain in FM patients with hypnotherapy (Huynh, Yanni, & Morgan, 2008) **(Grade B, Evidence Fair)**.
6. Biofeedback. Biofeedback has been shown to help overcome apparent imbalances in the autonomic nervous system, a primary component of the response to stress (Horowitz, 2008) **(Grade B, Evidence Fair)**.
7. Balneotherapy. This therapy involves bathing in mineral-rich water. It may involve hot or cold water or massage via moving water. Studies show moderate reduction of fibromyalgia symptoms (Goldenberg, Burckhardt, & Crofford, 2004) **(Grade B, Evidence Fair)**.

The following nonpharmacologic treatments have shown little or no evidence in efficacy for fibromyalgia treatment:

- Chiropractic therapy
- Massage therapy
- Electrotherapy
- Ultrasound
- Trigger point injections
- Flexibility exercise

(Huynh, Yanni, & Morgan, 2008) **(Grade C, Evidence Fair)**

Step 3 — Pharmacological Therapy

Pharmacologic treatment of FM involves targeting a variety of symptoms, often with medications from multiple classes (Goldenberg, Burckhardt, & Crofford, 2004). While there are only 3 medications which are U.S. Food and Drug Administration (FDA)-approved for FM treatment (duloxetine, pregabalin, and milnacipran), there are varying levels of evidence for the off-label use of many pharmacologic agents in FM management (Hauser et al., 2009) **(Grade A, Evidence Good)**.

Antidepressants

Antidepressants have demonstrated improvement in sleep, fatigue, pain, and well-being in patients with FM. The tricyclic antidepressants (TCAs) and serotonin-norepinephrine reuptake inhibitors have shown the most improvement in symptoms (Huynh, Yanni, & Morgan, 2008).

1. Tricyclic Antidepressants (TCAs)
    - Amitriptyline: Meta-analyses of several randomized controlled trials (RCTs) found efficacy for the use of amitriptyline in the treatment of FM pain, fatigue, and sleep disturbance (Arnold, Keck & Welge, 2000; O'Malley et al., 2000). Start amitriptyline at 10 mg at bedtime (HS) and titrate up slowly by 10 mg weekly to the highest therapeutic dose the patient can tolerate (max 50 mg/day) (Hauser et al., 2009) **(Grade A, Evidence Good)**.
2. Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)
    - Duloxetine: Duloxetine is FDA approved and has been shown to improve FM associated pain, fatigue, stiffness, and quality of life (Arnold et al., 2004; Russell et al., 2008). Dosing should be initiated at 30 mg/day and titrated weekly up to the highest therapeutic dose the patient can tolerate to a maximum of 120 mg/day (Goldenberg, 2009). An advantage of duloxetine is that it may treat comorbid depression common in fibromyalgia patients (Clauw, 2008) **(Grade A, Evidence Good)**.
    - Milnacipran: FDA approved in January 2009 for the treatment of FM. Two RCTs showed improvement in FM pain, fatigue, and physical function with use of milnacipran (Gendreau et al., 2005; Clauw et al., 2008). Administer milnacipran in two divided doses per day. Begin dosing at 12.5 mg on the first day and increase to 100 mg/day over a 1-week period. Recommended dose is 100 mg/day. May be increased to 200 mg/day based on individual patient response ("EULAR issues guidelines," 2008) **(Grade A, Evidence Good)**.
    - Venlafaxine: A small study using a flexible dose design with the final mean dose being 167mg/day showed this dual uptake inhibitor may be effective (Sayar et al., 2003) **(Grade C, Evidence Fair)**.
3. Selective Serotonin Reuptake Inhibitors (SSRIs)
    - Citalopram: This SSRI did not show sustainable efficacy in treating symptoms of FM (Huynh, Yanni, & Morgan, 2008) **(Grade D, Evidence Fair)**.
    - Fluoxetine: One RCT found fluoxetine 10 to 80 mg/day to improve FM pain and other outcome measures (Arnold et al., 2002). Dose

escalation from 20 to a maximum of 80 mg/day has been shown to be effective for FM pain (Goldenberg, 2009) **(Grade B, Evidence Fair)**.

- Paroxetine: Paroxetine controlled release (CR) 12.5 to 62.5 mg daily was found to be effective in improving FIQ scores in FM patients in the largest RCT study to date (Patkar et al., 2007) **(Grade B, Evidence Fair)**.

Anticonvulsants

1. Gabapentin: One recent RCT showed improved scores on the Brief Pain Inventory and FIQ in FM patients with use of gabapentin 1200 to 2400 mg/day (Arnold et al., 2007) **(Grade B, Evidence Fair)**. Start with 300 mg HS and titrate upward by 300 mg/day to desired effect (Clauw, 2008) **(Grade I, Evidence Poor)**.
2. Pregabalin: This medication is FDA approved for fibromyalgia. 300 to 450 mg daily showed improved pain, fatigue, sleep, and global well-being in one RCT (Crofford et al., 2005). Initial dosing is typically 75 mg twice daily (BID) and is increased to 150 mg BID over 7 days (Goldenberg, 2009) **(Grade A, Evidence Good)**.

Other Medications

1. Cyclobenzaprine: Cyclobenzaprine is a muscle relaxer with a chemical structure similar to the TCAs. One meta-analysis of several studies showed improvement in sleep quality with modest changes in tender points, stiffness, and fatigue (Tofferi, Jackson, & O'Malley, 2004). Initial dosing of 5 mg HS may lessen side effects, and titration up to 20 mg/day may be necessary (Huynh, Yanni, & Morgan, 2008) **(Grade B, Evidence Good)**.
2. Tramadol: Studies have shown mixed results on the efficacy of tramadol used as monotherapy in FM pain (Russell et al., 2000). Evidence for tramadol/acetaminophen (APAP) combination therapy is better than for tramadol alone (Bennett et al., 2003). Dosages of 50 to 100 mg every 6 hours are typically recommended (Goldenberg, 2009) **(Grade C, Evidence Fair)**.
3. Opioids, benzodiazepines, non-steroidal anti-inflammatory drugs (NSAIDs), magnesium, guaifenesin, and hormonal agents (thyroxine, dehydroepiandrosterone [DHEA], melatonin, calcitonin) have not been shown to be effective or recommended for treatment of FM. (Huynh, Yanni, & Morgan, 2008) **(Grade C, Evidence Poor)**.

Definitions:

Quality of Evidence (Based on U.S. Preventive Services Task Force [USPSTF] Ratings)

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individual studies, generalizability to routine practice, or indirect nature of the evidence of health outcomes.

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Grading of Recommendations (Based on USPSTF Ratings)

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is identified and graded for all recommendations (see "Major Recommendations").

These recommendations were based primarily on sources such as national guidelines, meta-analysis review, and evidence-based, randomized, controlled research studies.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improved treatment and management and quality of life of patients with fibromyalgia syndrome
- Decreased cost of care

POTENTIAL HARMS

Adverse Effects of Medications

All medications mentioned in this guideline carry the potential of adverse side effects. Providers should consider treatment decisions based on thorough assessment of a patient's history and physical exam findings. The guideline developers strongly recommend that prescribers consult the Physicians' Desk Reference or other reliable source of drug information to familiarize themselves with the potential adverse effects of all medications they prescribe.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Known hypersensitivity to any drug/class/component mentioned in this guideline
- Contraindications to *amitriptyline* include monoamine oxidase (MAO) inhibitor use within 14 days and acute recovery from myocardial infarction. Avoid abrupt withdrawal.
- Contraindications to *duloxetine* include MAO inhibitor use within 14 days, hepatic dysfunction, chronic alcohol abuse, uncontrolled angle-closure glaucoma. Avoid abrupt withdrawal.
- Contraindications to *venlafaxine* and *paroxetine* include MAO inhibitor use within 14 days. Avoid abrupt withdrawal.
- Contraindications to *fluoxetine* include MAO inhibitor use within 5 weeks. Avoid abrupt withdrawal.
- Contraindications to *cyclobenzaprine* include MAO inhibitor use with 14 days, acute recovery from myocardial infarction, hyperthyroidism, arrhythmias, heart block, congestive heart failure (CHF), cardiac conduction disturbances. Avoid abrupt withdrawal after long-term use.
- Contraindications to *tramadol* include acute drug/alcohol intoxication, history of opioid anaphylaxis. Lowers the seizure threshold. Avoid abrupt withdrawal.

QUALIFYING STATEMENTS

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- These guidelines are not intended for use outside the stated population.
- The independent skill and judgment of the healthcare provider must always dictate treatment decisions.

- These practice guidelines are meant to serve as a general framework for managing clients with fibromyalgia syndrome. It may not always be appropriate to use these guidelines to manage clients because individual circumstances may vary. For example, different treatments may be appropriate for clients who are severely ill or who have comorbid, socioeconomic, or other complicating conditions.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

University of Texas, School of Nursing, Family Nurse Practitioner Program. Management of fibromyalgia syndrome in adults. Austin (TX): University of Texas, School of Nursing; 2009 May. 14 p. [25 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2009 May

GUIDELINE DEVELOPER(S)

University of Texas at Austin School of Nursing, Family Nurse Practitioner Program - Academic Institution

SOURCE(S) OF FUNDING

University of Texas at Austin, School of Nursing, Family Nurse Practitioner Program

GUIDELINE COMMITTEE

Practice Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Christine Guidroz, RN, BSN; Julie Isaac, RN, BSN; Brian King, RN, MSN; Karen Laird, RN, BSN

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

None stated

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This guideline updates a previous version: University of Texas, School of Nursing, Family Nurse Practitioner Program. Fibromyalgia treatment guideline. Austin (TX): University of Texas, School of Nursing; 2005 May. 13 p. [18 references]

GUIDELINE AVAILABILITY

Electronic copies: None available.

Print copies: Available from the University of Texas at Austin, School of Nursing. 1700 Red River, Austin, Texas, 78701-1499

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on February 5, 2010. The information was verified by the guideline developer on April 26, 2010.

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